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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT PAPER NUMBER

1651

DATE MAILED: 07/02/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/392,243

Applicant(s)

LEE ET AL.

Examiner

Francisco C Prats

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 21-27 and 36-54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-27 and 36-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

Art Unit: 1651

**DETAILED ACTION**

The amendment filed April 11, 2002, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 1-20 and 28-35 have been cancelled.

Claims 36-54 have been added.

Claims 21-27 and 36-54 are pending and are examined on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 is confusing, and therefore indefinite in two aspects. First, claim 42 recites "the improvement of claim 36" whereas claim 36 does not recite any "improvement." Secondly, it is confusing what the claim is intending to recite since it

Art Unit: 1651

recites addition of a product to a composition, but then recites that the added product must become undetectable.

***Claim Rejections - 35 USC § 103***

Claims 21-27 and 36-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Gorp et al (U.S. Pat. 5,607,840) in view of Balslev et al (U.S. Pat. 4,438,100) and Oles (U.S. Pat. 4,145,451).

Van Gorp discloses a process wherein a mucosal protein hydrolysate is added to protein-containing food or feed. Van Gorp also discloses the preservation of the mucosa starting material using well known preservatives. See col. 4, lines 17-34 and 45-50. Note specifically Van Gorp's disclosure of the suitability of a heating step in the preservation methods as recited in applicant's claims 24, 43 and 44. Note further that because it contains the same material, mucosa, Van Gorp's preserved product would inherently have the same ash amount as recited in the claims.

Van Gorp differs from the claims in that Van Gorp does not use the claimed peroxide or phosphoric acid as a preservative. However, each of Oles (see, e.g., abstract) and Balslev (see, e.g., abstract) make it clear that both phosphoric acid and peroxide were well known preservatives in food and/or

Art Unit: 1651

pharmaceutical applications. Thus, the claimed substitution of well known preservatives for those used in Van Gorp must be considered an obvious substitution of one known equivalent preservative for another. That is, because the artisan of ordinary skill at the time of applicant's invention would have had a reasonable expectation from Oles and Balslev that phosphoric acid and/or peroxide would have functioned equivalently to the preservatives disclosed by Van Gorp, the artisan of ordinary skill would have been motivated to have substituted Oles' phosphoric acid and/or Balslev's peroxide for the preservatives disclosed by Van Gorp.

It is noted that Van Gorp does not disclose the bacterial count of the preserved mucosa product, as recited in applicant's claims 26 and 27. However, because the entire objective of adding preservatives according to Van Gorp's disclosure is the prevention of bacterial growth in the mucosa products, it is respectfully submitted that the determination of an acceptable degree of preservation as measured by bacterial contamination would have been a matter of routine optimization on the part of the artisan of ordinary skill, the degree of bacterial contamination clearly being a result-effective parameter optimized by adding more or less preservative agent. Thus, absent some demonstration of an unexpected result inhering from

Art Unit: 1651

the claimed process, a holding of obviousness under § 103(a) is clearly required.

### ***Response to Arguments***

All of applicant's argument has been fully considered but is not persuasive of error. Applicant argues that the obviousness rejection of record fails to take into account information critical to the required analysis, and which teaches away from the claimed invention. Specifically, applicant urges that because Balslev discloses that hydrogen peroxide is effective at eliminating mucine-decomposing enzymatic activity, Balslev teaches away from substituting hydrogen peroxide for Van Gorp's oxygen-scavenging preservatives.

Applicant's analysis does not recognize the fact that hydrogen peroxide continuously decomposes, eventually to a concentration of zero, after addition as a preservative to a composition. See Balslev at col. 6, lines 39-68:

Thus it is characteristic to the sterilization and preservation with these oxidizing bactericides that the relatively high initial concentration thereof used in the sterilization process decreases rapidly during the initial short period whereafter a physiologically tolerable, but still bactericidally effective concentration is retained during the following storage and application period.

Thus, rather than teaching away from using peroxide,

Art Unit: 1651

Balslev's disclosure makes it clear that peroxide is an ideal sterilizing and preservative agent for storage applications, such as Van Gorp's, because of its property of decomposition over time. Moreover, given the fact that it will decompose during storage, the artisan of ordinary skill would not expect the amount of peroxide remaining after storage to affect the mucosa-hydrolyzing enzymes used in Van Gorp, contrary to applicant's argument. Further still, applicant fails to provide any direct evidence suggesting that using Balslev's amounts of hydrogen peroxide to sterilize Van Gorp's mucosa compositions will in fact inhibit Van Gorp's process.

Applicant further argues that Van Gorp would not have been motivated to use peroxide as the preservative agent because he was concerned mostly with ash reduction, and neither Van Gorp nor Balslev discloses anything about ash reduction. However, Van Gorp discloses that a preservative should be used to store his mucosa starting materials, and Balslev discloses that hydrogen peroxide is an excellent preservative. Thus, motivation for using Balslev's peroxide in Van Gorp's composition is readily apparent.

Regarding Balslev and Van Gorp, applicant further argues that because Balslev employs his preservative in a manner different than Van Gorp, one would not have been motivated to

Art Unit: 1651

have used Balslev's peroxide in Van Gorp's process. This is simply not persuasive. Clearly the artisan of ordinary skill would have known how to apply Balslev's peroxide in Van Gorp's process.

With respect to Oles, applicant argues initially that Van Gorp's failure to list phosphoric acid as a suitable preservative teaches away from the use of Oles' phosphoric acid in Van Gorp's compositions.

Applicant's argument employs an incorrect standard of obviousness. The standard by which obviousness is determined is whether the claimed subject matter would have been obvious "to a person having ordinary skill in the art to which said subject matter pertains", not whether the author of a particular prior art publication actually combined his or her technical pursuit with another piece of prior art. See 35 U.S.C. § 103(a). Moreover, the assessment of obviousness is made from the viewpoint of "the time the invention was made", not at the time a particular piece of prior art is published. See *id.*

Applicant's analysis of why Van Gorp did not use peroxide or phosphoric acid therefore does not apply the correct criteria required for an obviousness determination. As discussed above, the standard is what the artisan of ordinary skill, at the time of applicant's invention, considered obvious, not what Van Gorp



Art Unit: 1651

considered obvious. Thus, "charging" the author of one prior art disclosure with the teaching of another prior art disclosure based on publication dates, and allegedly demonstrating non-obviousness by the first author's failure to combine his teaching with the that of the second piece of prior art, is clearly not the standard of obviousness. The fact that Van Gorp did not disclose the use of the peroxide of Balslev or the phosphoric acid of Oles demonstrates only one thing -- that Van Gorp does not anticipate the claims. Accepting applicant's "charging" argument would mean that no prior art disclosures could ever be combined, clearly contrary to established practice under 35 U.S.C. § 103(a).

Applicant further argues that one would not have been motivated to have substituted Oles' phosphoric acid for the preservatives disclosed in Van Gorp because the two preservatives are used in allegedly very different manners, to preserve very different materials, which make the substitution alleged in the rejection of record "obvious to try" at best.

However, obviousness does not require absolute predictability. Rather, the prior art need only provide the artisan of ordinary skill a reasonable expectation of success. See MPEP 2143.02. From Oles' disclosure of the suitability of phosphoric acid as a preservative in food applications, the

Art Unit: 1651

artisan of ordinary skill clearly would have reasonably expected it to be useful in Van Gorp's process.

Applicant further argues that Van Gorp would not have been motivated to use phosphoric acid as the preservative agent because he was concerned mostly with ash reduction, and neither Van Gorp nor Oles discloses anything about ash reduction. However, Van Gorp discloses that a preservative should be used to store his mucosa starting materials, and Oles discloses that phosphoric is an excellent preservative. Thus, motivation for using Oles' phosphoric acid in Van Gorp's composition is readily apparent.

Applicant further argues that because claim 21 recites only hydrogen peroxide and phosphoric acid in the Markush group listing suitable preservatives, and because Oles uses a combination of phosphoric acid and acetic acid as preservative agents, Oles does not suggest the claimed process. This argument ignores the fact that the process is recited in open "comprising" language which encompasses the addition of anything to the composition, including the acetic acid disclosed in Oles. While the claims clearly require that hydrogen peroxide or phosphoric acid be added to the mucosa, they do not exclude the addition of other ingredients, such as acetic acid. Thus, applicant's argument ignores the actual limitations present in

Art Unit: 1651

the claims.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

Art Unit: 1651

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Francisco C Prats  
Primary Examiner  
Art Unit 1651

FCP  
June 28, 2002